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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,426	03/25/2005	Ferdinand Hermann Bahlmann	P/2107-264	5804
2352 7590 09/17/2007 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			EXAMINER HEARD, THOMAS SWEENEY	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 09/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/522,426

Applicant(s)

BAHLMANN ET AL.

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-107 is/are pending in the application.
- 4a) Of the above claim(s) 44, 45, 47-51, 54-58, 60-64, 66-69, 71-89, and 91-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46, 52, 53, 59, 65, 70 and 90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/DS.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group III, Claims 46, 52, 53, 59, 65, 70, and 90, in the reply filed on 7/26/2007 is acknowledged. Applicants have stated that they have elected Group III with traverse but have not provided a reason in which the restriction was improper and would not be a burden. Therefore, the election is treated as being without traverse.

Claims 44, 45, 47-51, 54-58, 60-64, 66-69, 71-89, and 91-107 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Claims 46, 52, 53, 59, 65, 70, and 90 are hereby examined on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46, 52, 53, 59, 65, 70, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fatouros MS et al "Influence of growth factors erythropoietin and granulocyte macrophage colony stimulating factor on mechanical strength and healing of colonic anastomoses in rats," Eur J Surg. 1999 Oct;165(10):986-92(from Applicant's IDS); Krussel JS, et al, "Vascular endothelial growth factor (VEGF) mRNA

splice variants are differentially expressed in human blastocysts," Mol Hum Reprod. 2001 Jan;7(1):57-63, Amgen Inc, EP 0613683 A1; and Zaharia Czeizler, US 6,274,158.

The instantly claimed invention is drawn to a method for wound healing through the administration of erythropoietin (EPO) and an ingredient that stimulates endothelial progenitor cells. Fatouros MS et al teaches the administration of EPO which was shown to be beneficial for healing of colonic anastomoses (the joining and suturing of two sections of intestine in which the cut intestine is viewed as a wound), readable on Claim 1 and 90. Recombinant EPO was administered via subcutaneous injection, readable upon Claims 52 and 53. Fatouros MS does not teach a weekly dosis of 1 to 90 IU of EPO/kg, pulmonary administration of EPO, oral administration of EPO, or an additional ingredient that stimulates endothelial progenitor cells.

Zaharia Czeizler, US 6,274,158, teaches the oral, subcutaneous, and intravenous administration of EPO for the treatment of bleeding due to surgical treatments, for example, see abstract and claim 32 for example. Amgen Inc, EP 0613683 A1, teaches EPO formulation for inhalers (Pulmonary administration), see abstract. Zaharia Czeizler and Amgen's references are readable upon Claims 59, 65, and 90

Krussel JS, et al teaches the compound VEGF (vascular endothelial growth factor) that is stimulate endothelial progenitor cells and induced angiogenesis, see Introduction and column 2, and is readable on Claim 70. Applicants have define wound healing as: *"In connection with the present invention, 'wound healing' means the physiological processes for regenerating damaged tissue and for closing a wound,*

*especially formation of new connective tissue and capillaries.*" Therefore, VEGF is viewed as a compound that not only is a compound that induces angiogenesis (capillary formation) but is also a compound that heals wound by Applicant's definition

It would have been obvious at the time of instantly claimed invention to use EPO in combination with VEGF for wound healing. One would have been motivated to do so given Fatouros' clear teaching of wound healing properties of EPO and Krussel's teaching that VEGF induces angiogenesis, an important part of wound healing from Applicant's definition of wound healing. Although Fatouros does not teach a method of using a composition comprising the specifically claimed concentration of the compounds for wound healing and at the particular dosage of 1 to 90 IU EPO/kg, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the concentration for administration of EPO for different wounds and different formulations and routes of administration taught by all four references of Fatouros, Zaharia Czeizler, Krusse, and Amgen. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46, 52, 53, 59, 65, 70, and 90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4, 15-31, 35-44 of copending Application No. 10/586,896. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant Application is drawn to the use of EPO for the purpose of wound healing. The 10/586,896 Application is drawn to the use of (which the Examiner is interpreting to mean a method of) EPO for the treatment of wound, specifically wound healing in addition to a combination therapy of EPO with VEGF. Oral, parenteral, and pulmonary (aerosol) administration are also claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP, 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

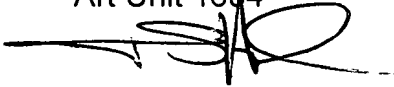
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

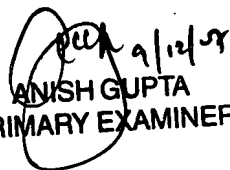
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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